## Amendments to the Specification

On page 9, lines 7-28, please replace the existing paragraph with the following substitute paragraph:

FIGURE 1 is a block diagram showing an automated collection and

5    analysis patient care system 10 for diagnosing and monitoring respiratory
insufficiency in accordance with the present invention. An exemplary automated
collection and analysis patient care system suitable for use with the present
invention is disclosed in the related, commonly assigned U.S. Patent No.
6,312,378, issued November 6, 2001, the disclosure of which is incorporated

10   herein by reference. Preferably, an individual patient 11 is a recipient of an
implantable medical device 12, such as, by way of example, an IPG,
cardiovascular, heart failure monitor, pulmonary monitor, or therapeutic device,
with a set of leads extending into his or her heart and electrodes implanted
throughout the cardiopulmonary system. Alternatively, an external monitoring or

15   therapeutic medical device [[26]] 28, a subcutaneous monitor or device inserted
into other organs, a cutaneous monitor, or even a manual physiological
measurement device, such as an respiratory monitor, electrocardiogram or heart
rate monitor, could be used. The implantable medical device 12 and external
medical device [[26]] 28 include circuitry for recording into a short-term, volatile

20   memory telemetered signals stored for later retrieval, which become part of a set
of device and derived measures, such as described below, by way of example,
with reference to FIGURE 2. Exemplary implantable medical devices suitable for
use in the present invention include the Discovery line of pacemakers,
manufactured by Guidant Corporation, Indianapolis, Indiana, and the Gem line of

25   ICDs, manufactured by Medtronic Corporation, Minneapolis, Minnesota.

On page 9, line 29 through page 10, line 17, please replace the existing paragraph with the following substitute paragraph:

The telemetered signals stored in the implantable medical device 12 are

preferably retrieved upon the completion of an initial observation period and subsequently thereafter on a continuous, periodic (daily) basis, such as described in the related, commonly assigned U.S. Patent No. 6,221,011, issued April 24, 2001, the disclosure of which is incorporated herein by reference. A programmer

5  14, personal computer 18, or similar device for communicating with an implantable medical device 12 can be used to retrieve the telemetered signals. A magnetized reed switch (not shown) within the implantable medical device 12 closes in response to the placement of a wand 13 over the site of the implantable medical device 12. The programmer 14 sends programming or interrogating

10  instructions to and retrieves stored telemetered signals from the implantable medical device 12 via RF signals exchanged through the wand 13. Similar communication means are used for accessing the external medical device [[26]] 28. Once downloaded, the telemetered signals are sent via an internetwork 15, such as the Internet, to a server system 16 which periodically receives and stores

15  the telemetered signals as device measures in patient care records 23 in a database 17, as further described below, by way of example, with reference to FIGURES 2 and 3. An exemplary programmer 14 suitable for use in the present invention is the Model 2901 Programmer Recorder Monitor, manufactured by Guidant Corporation, Indianapolis, Indiana.

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On page 10, line 18 through page 11, line 5, please replace the existing paragraph with the following substitute paragraph:

The patient 11 is remotely monitored by the server system 16 via the internetwork 15 through the periodic receipt of the retrieved device measures

25  from the implantable medical device 12 or external medical device [[26]] 28. The patient care records 23 in the database 17 are organized into two identified sets of device measures: an optional reference baseline 26 recorded during an initial observation period and monitoring sets 27 recorded subsequently thereafter. The device measures sets are periodically analyzed and compared by the server system

30  16 to indicator thresholds corresponding to quantifiable physiological measures of

a pathophysiology indicative of respiratory insufficiency, as further described below with reference to FIGURE 5. As necessary, feedback is provided to the patient 11. By way of example, the feedback includes an electronic mail message automatically sent by the server system 16 over the internetwork 15 to a personal

5 computer 18 (PC) situated for local access by the patient 11. Alternatively, the feedback can be sent through a telephone interface device 19 as an automated voice mail message to a telephone 21 or as an automated facsimile message to a facsimile machine 22, both also situated for local access by the patient 11. Moreover, simultaneous notifications can also be delivered to the patient's

10 physician, hospital, or emergency medical services provider 29 using similar feedback means to deliver the information.

On page 12, line 1 through page 12, line 1, please replace the existing paragraph with the following substitute paragraph:

15      The implantable medical device 12 and, in a more limited fashion, the external medical device [[26]] 28, record patient information for care of patients with respiratory insufficiency on a regular basis. The recorded patient information is downloaded and stored in the database 17 as part of a patient care record 23. Further patient information can be derived from recorded data, as is

20 known in the art. FIGURE 2 is a database schema showing, by way of example, the organization of a device and derived measures set record 40 for patient care stored as part of a patient care record in the database 17 of the system of FIGURE 1. Each record 40 stores patient information which includes a snapshot of telemetered signals data which were recorded by the implantable medical device

25 12 or the external medical device [[26]] 28, for instance, on per heartbeat, binned average or derived bases; measures derived from the recorded device measures; and manually collected information, such as obtained through a patient medical history interview or questionnaire. The following non-exclusive information can be recorded for a patient: atrial electrical activity 41, ventricular electrical activity

30 42, PR interval or AV interval 43, QRS measures 44, ST-T wave measures 45,

QT interval 46, body temperature 47, patient activity score 48, posture 49, cardiovascular pressures 50, pulmonary artery systolic pressure measure 51, pulmonary artery diastolic pressure measure 52, respiratory rate 53, ventilatory tidal volume 54, minute ventilation 55, transthoracic impedance 56, cardiac

5     output 57, systemic blood pressure 58, patient geographic location (altitude) 59, mixed venous oxygen score 60, arterial oxygen score 61, arterial carbon dioxide score 62, acidity (pH) level 63, potassium [K+] level 64, sodium [Na+] level 65, glucose level 66, blood urea nitrogen (BUN) and creatinine 67, hematocrit 68, hormonal levels 69, lung injury chemical tests 70, cardiac injury chemical tests

10    71, myocardial blood flow 72, central nervous system (CNS) injury chemical tests 73, central nervous system blood flow 74, interventions made by the implantable medical device or external medical device 75, and the relative success of any interventions made 76. In addition, the implantable medical device or external medical device communicates device-specific information, including battery

15    status, general device status and program settings 77 and the time of day 78 for the various recorded measures. Other types of collected, recorded, combined, or derived measures are possible, as is known in the art.

On page 13, line 16 through page 14, line 2, please replace the existing paragraph
20    with the following substitute paragraph:

As an adjunct to remote patient care through the monitoring of measured physiological data via the implantable medical device 12 or external medical device [[26]] 28, quality of life and symptom measures sets 25a can also be stored in the database 17 as part of the reference baseline 26, if used, and the monitoring
25    sets 27. A quality of life measure is a semi-quantitative self-assessment of an individual patient's physical and emotional well being and a record of symptoms, such as provided by the Duke Activities Status Indicator. These scoring systems can be provided for use by the patient 11 on the personal computer 18 (shown in FIGURE 1) to record his or her quality of life scores for both initial and periodic
30    download to the server system 16. FIGURE 3 is a database schema showing, by

way of example, the organization of a quality of life record 80 for use in the database 17. The following information is recorded for a patient: overall health wellness 81, psychological state 82, activities of daily living 83, work status 84, geographic location 85, family status 86, shortness of breath 87, cough 88, sputum

5    production 89, sputum color 90, energy level 91, exercise tolerance 92, chest discomfort 93, and time of day 94, and other quality of life and symptom measures as would be known to one skilled in the art.

On page 24, lines 18-22, please replace the existing paragraph with the following

10   substitute paragraph:

For any given patient, three basic types of comparisons between individual measures stored in the monitoring sets 27 are possible: self referencing, peer group, and general population, as explained above with reference to FIGURE 6. In addition, each of these comparisons can include comparisons to individual

15   measures stored in the pertinent reference baselines [[24]] 26.

On page 30, line 3-15, please replace the existing paragraph with the following substitute paragraph:

As primary pulmonary disease considerations, multiple individual

20   indications (blocks 240-243, ~~245-253~~ 245-255) should be present for the two principal findings of respiratory insufficiency related reduced exercise capacity (block 244), or respiratory insufficiency related respiratory distress (block 256), to be indicated, both for disease onset or progression. The presence of primary key findings alone can be sufficient to indicate an onset of respiratory insufficiency

25   and secondary key findings serve to corroborate disease onset. Note the presence of any abnormality can trigger an analysis for the presence or absence of secondary disease processes, such as the presence of atrial fibrillation or congestive heart failure. Secondary disease considerations can be evaluated using the same indications (see, e.g., blocks 141-144 of FIGURES 8A-8B), but with

adjusted indicator thresholds 129 (shown in FIGURE 5) triggered at a change of 0.5 SD, for example, instead of 1.0 SD.

On page 30, lines 16-29, please replace the existing paragraph with the following

5    substitute paragraph:

In the described embodiment, the reduced exercise capacity and respiratory distress findings (blocks 244, [[251]] 256) can be established by consolidating the individual indications (blocks 240-243, 245-253 245-255) in several ways. First, in a preferred embodiment, each individual indication (blocks

10    240-243, 245-253 245-255) is assigned a scaled index value correlating with the relative severity of the indication. For example, decreased cardiac output (block 240) could be measured on a scale from '1' to '5' wherein a score of '1' indicates no change in cardiac output from the reference point, a score of '2' indicates a change exceeding 0.5 SD, a score of '3' indicates a change exceeding 1.0 SD, a

15    score of '4' indicates a change exceeding 2.0 SD, and a score of '5' indicates a change exceeding 3.0 SD. [[.]] The index value for each of the individual indications (blocks 240-243, 245-253 245-255) can then either be aggregated or averaged with a result exceeding the aggregate or average maximum indicating an appropriate respiratory insufficiency finding.

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On page 31, lines 8-11, please replace the existing paragraph with the following substitute paragraph:

Alternatively, a simple binary decision tree can be utilized wherein each of the individual indications (blocks 240-243, 245-253 245-255) is either present or

25    is not present. All or a majority of the individual indications (blocks 240-243, 245-253 245-255) should be present for the relevant respiratory insufficiency finding to be affirmed.

On page 31, lines 12-13, please replace the existing paragraph with the following

substitute paragraph:

Other forms of consolidating the individual indications (blocks 240-243, ~~245-253~~ 245-255) are feasible.

5      On page 31, line 24 through page 32, line 2, please replace the existing paragraph with the following substitute paragraph:

Similarly, FIGURES 15A-15C are flow diagrams showing the routine for determining a regression or improving of respiratory distress 235 for use in the routine of FIGURE 12.  The same factors as described above with reference to

10     FIGURES 13A-13C and 14A-14C, trending in opposite directions from disease onset or progression, are evaluated to determine disease regression.  As primary cardiac disease considerations, multiple individual indications (blocks 300-303, ~~305-313~~ 305-315) should be present for the two principal findings of respiratory insufficiency related reduced exercise capacity (block 304), or respiratory

15     insufficiency related respiratory distress (block 316), to indicate disease